DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the response filed 8 March 2010. 1, 12-13, 15-20, 24, 26-32, 36-44, 47, 53, 67, 73-80 are pending.

Claims 1, 12-13, 15-20, 24, 26-32, 36-44, 47, 53, 67, 73-80 are maintained as set forth in the previous Office Action mailed 8 September 2009, herein incorporated by reference. Applicant's remarks are addressed below.

Claim Rejections - 35 USC § 112

[2] Previous rejection of claims1-4, 6-24, and 26-56 rejected under 35 U.S.C. 112, second paragraph, set forth in the Office Action mailed 20 May 2008 have been withdrawn.

Specification

[3] The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

A substitute specification replacing the document submitted 2 April 2002 is required pursuant to 37 CFR 1.125(a) because the Specification as filed presents a singular document in which the claims, drawings, and description of the invention are not presented in separate sheets.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Response to Remarks

Applicant's remarks filed 8 March 2010 have been fully considered but they are not persuasive. The remarks will be addressed below in the order in which they appear in the noted response.

Applicant remarks that claims 1, 12, 13, 15, 17-18, 20, 24, 26-32, 34, 47, 53, 67, and 73-80 are non-obvious over DeLaHuerga, alone or in combination.

Specifically, Applicant remarks:

"[Mishelvich reference fails to disclose]...a medicament delivery system that is arranged to provide respirable delivery of a dose of medicament to a patient, which dose may be varied"

Applicant further remarks:

"...Mishelvich teaches away from varying the dose delivered by the inhaler...[but] refers to delivering a fixed amount of medication from the inhaler...".

Applicant further remarks:

"...[Michelvich discloses] a standard metered-dose inhaler...The skilled person known that a standard MDI canister is designed to deliver a fixed dose...It is therefore considered that "alter the dosage" [disclosed in Mishelvich] refers to changing the target envelop..."

In response to the remarks noted above, Examiner respectfully disagrees and initially notes the language of method claim 47 as presented. With respect to the varying of a dose, Claim 47 recites "varying the dose of medicament to be delivered by the medicament delivery system in response to data received….from the network computer system…"

While Applicant provides secondary commentary indicating that the "varying" is responsive to the respiratory data, the claim as presented requires varying a dose "to be delivered" from the network. As presented, the noted varying is neither actually performed nor is it sufficiently tied to the respiratory data collected by the sensor but is rather tied simply to "data from the network". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns,* 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Considering the noted "varying" limitation in light of the Specification as originally filed, specific disclosure regarding the inhaler indicates that the inhaler "…is a standard-form metered

dose inhaler" (Specification' page 19). Examiner notes that this inhaler appears to be the same metered-dose type of inhaler, which, as discussed by Applicant, is employed by Mishelvich.

In further response, the Specification further provides with respect to varying the dosage, "information received from any of the remote information sources have be utilized by the electronic data management system to vary the recommended dose for delivery to the patient..." (Specification; page 19). The language "vary the recommended dose to the patient..." does not indicate varying the dose administered by the inhaler when considered in light of the Specification. Accordingly, as claimed and supported by the Specification, the varying feature of the instant invention appears to be the same as disclosed by Mishelvich.

In conclusion, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 8 March 2010 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of the applied references, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (8 September 2009), and incorporated herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[4] Claims 1, 12-13, 15, 17-18, 20, 24, 26-32, 34, 47, 53, 67, and 73-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLaHuerga (United States Patent #6,408,330) in view of McKinnon et al. (United States Patent #6,190,326) and further in view of Mishelvich et al. (United States Patent #5,363,842) as presented in the previous Office Action mailed 8 September 2009 herein incorporated by reference.

[5] Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable in consideration of DeLaHuerga in view of McKinnon et al. and further in view of Mishelvich et al. as applied to claim 1 above and further in view of Admitted Prior Art, as presented in the previous Office Action mailed 8 September 2009 herein incorporated by reference.

[6] Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLaHeurga,, in view of McKinnon et al. in view of Mishelvich et al. as applied to claim 1 above, and further in view of Thompson, (U.S. 6,083,248), as presented in the previous Office Action mailed 8 September 2009 herein incorporated by reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David Rines whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Primary Examiner, Art Unit 3623